

examiner's action is contrary to the Patent Office's prohibition against piecemeal examination. *See* MPEP §707(g) (August 2001). Accordingly, applicants have filed a petition under 37 C.F.R. §1.181, seeking an invocation of the Commissioner's supervisory authority.

Claims 1, 2, 4-7, 9-13 and 16-18 are pending.

I. REJECTIONS UNDER 35 U.S.C. § 112 ¶2

The examiner rejects claims 1, 6, 9-13 and 17-18 under 35 U.S.C. §112, ¶2 for alleged indefiniteness. Applicants respectfully traverse the rejection.

Applicants assert that, in view of the teachings of the specification, one skilled in the art would understand the meaning of the term "anti-CD3 active compounds" and, thus, the breadth of the claimed invention. In fact, the previous examiner, in accepting the amended term, acknowledged that the term distinctly described the claimed subject matter. Accordingly, Applicants request that the rejection be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. § 112 ¶1

The examiner rejects claims 1, 2, 4-7, 9-13 and 16-18 under 35 U.S.C. §112, ¶1 for allegedly failing to enable one of ordinary skill in the art to make and use the invention. Applicants respectfully traverse the rejection.

To support his enablement rejection, the examiner points to a lack of human testing. As the examiner must know, human testing *per se* is not a requirement for patentability. Instead, §112 requires an application to show how to "make and use" the claimed invention. The courts have interpreted this statute to mean that the specification must teach the skilled artisan how to practice the invention without undue experimentation. *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). Thus, the test is not whether experimentation is necessary, but whether any experimentation would be undue in view of what type and amount of experimentation is typical in the area. *See In re Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). *See also* MPEP §2164.01 (Aug. 2001) at page 2100-174.

Since the early days of immunology, mice have been the standard model for immunological testing. Practitioners and courts, alike, have recognized the model's

ability to predict efficacy in humans. Moreover, adaptation of murine therapies to humans is among the more basic skills of the immunologist. Accordingly, as the examiner has failed to advance any reason why a person of ordinary skill in the art could not practice the inventive methods in humans without undue experimentation, applicants request that the rejection be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. § 103

The examiner rejects claims 1, 2, 4-6, and 16-18 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chatenoud *et al.* (1994). Applicants respectfully traverse the rejection.

While acknowledging that applicant's claim amendment vitiates the Board's new anticipation rejection, the examiner asserted out of hand that Chatenoud *et al.* "suggest that treatments like those disclosed for NOD mice should be applied to humans with diabetes." This contention is erroneous as a matter of law, however.

Contrary to the examiner's suggestion, the Board did not find that Chatenoud *et al.* taught a method of treating spontaneous and ongoing auto-immune diseases in mammals, comprising administering a therapeutically effective amount of one or more non-mitogenic anti-CD3 active compounds to achieve permanent disease remission through the induction of antigen-specific unresponsiveness. Rather, the board concluded that the method used by Chatenoud *et al.* inherently yielded the same result as the claimed invention. *See* Decision on Appeal, pg. 6, ¶2. While disagreeing with the Board's conclusion, applicants amended claim 1 to recite "human" rather than "mammal," thereby removing Chatenoud *et al.* as an anticipatory reference.

Moreover, the amendment completely removed Chatenoud *et al.* as a prior art reference. An inherent disclosure in a reference cannot support an obviousness rejection. *See In re Newell*, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."), *quoting In re Spormann*, 53 C.C.P.A. 1375, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Thus, the examiner erred as a matter of law in levying an obviousness rejection based on Chatenoud *et al.* Accordingly, applicants request that the rejection be withdrawn.

The examiner also rejects claims 1, 4 and 7 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chatenoud *et al.* in view of Gussow *et al.* Applicants respectfully traverse the rejection.

As noted above, as a matter of law, the examiner cannot levy against the instant claims an obviousness rejection based upon Chatenoud *et al.* Accordingly, applicants request that the rejection be withdrawn.

In view of the foregoing remarks, a favorable disposition of the application therefore is solicited. The examiner also is invited to contact the undersigned if there are any questions or if the examiner believes that further discussion will advance prosecution.

Respectfully submitted,

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Date

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